Complete Summary

GUIDELINE TITLE

Premenstrual syndrome.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Premenstrual syndrome. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2000 Apr. 9 p. (ACOG practice bulletin; no. 15). [60 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

* * REGULATORY ALERT * *

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On May 12, 2006, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Clinical Worsening and Suicide Risk subsection of the WARNINGS section in the prescribing Information for Paxil and Paxil CR. These labeling changes relate to adult patients, particularly those who are younger adults.

  A recent meta-analysis conducted of suicidal behavior and ideation in placebo-controlled clinical trials of paroxetine in adult patients with psychiatric disorders including Major Depressive Disorder (MDD), other depression and non-depression disorders. Results of this analysis showed a higher frequency of suicidal behavior in young adults treated with paroxetine compared with placebo. Further, in the analysis of adults with MDD (all ages), the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo. This difference was statistically significant; however, as the absolute number and incidence of events are small, these data should be interpreted with caution. All of the reported events of suicidal behavior in the adult patients with MDD were non-fatal suicide attempts, and the majority of these attempts (8 of 11) were in younger adults aged 18-30. These MDD data

suggest that the higher frequency observed in the younger adult population across psychiatric disorders may extend beyond the age of 24.

It is important that all patients, especially young adults and those who are improving, receive careful monitoring during paroxetine therapy regardless of the condition being treated. See the FDA Web site for more information.

- On December 8, 2005, the U.S. Food and Drug Administration (FDA) has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine's pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine's prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

  Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician. See the FDA Web site for more information.

- On September 27, 2005, GlaxoSmithKline (GSK) and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of changes to the Pregnancy/PRECAUTIONS section of the Prescribing Information for Paxil and Paxil CR Controlled-Release Tablets to describe the results of a GSK retrospective epidemiologic study of major congenital malformations in infants born to women taking antidepressants during the first trimester of pregnancy. This study suggested an increase in the risk of overall major congenital malformations for paroxetine as compared to other antidepressants [OR 2.2; 95% confidence interval, 1.34-3.63]. Healthcare professionals are advised to carefully weigh the potential risks and benefits of using paroxetine therapy in women during pregnancy and to discuss these findings as well as treatment alternatives with their patients. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Premenstrual syndrome

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To examine the evidence for commonly used approaches in the treatment of premenstrual syndrome (PMS) and identify those that are effective

TARGET POPULATION

Women with symptoms of premenstrual syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Medical and psychologic history
2. Physical examination
3. Prospective symptom diaries and/or calendars to confirm timing of symptoms

Treatment/Management

1. Supportive therapy, including reassurance and informational counseling and relaxation therapy
2. Aerobic exercise

3. Dietary supplements, including calcium, magnesium, vitamin E, vitamin B_6, carbohydrate-rich foods and beverages, and primrose oil
4. Selective serotonin reuptake inhibitors (SSRIs), including fluoxetine, sertraline, paroxetine, clomipramine, fluvoxamine, and nefazodone
5. Other pharmacological approaches, including use of alprazolam, spironolactone, and natural progesterone
6. Hormone suppression through oral contraceptives, gonadotropin-releasing hormone (GnRH) agonists, or bilateral salpingo-oophorectomy

MAJOR OUTCOMES CONSIDERED

Improvements in symptoms of premenstrual syndrome (PMS)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' (ACOG's) own internal resources were used to conduct a literature search to locate relevant articles published between January 1985 and May 1999. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations."

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women in whom premenstrual syndrome (PMS) has been diagnosed should meet standard diagnostic criteria and should have the timing of their symptoms confirmed using a prospective symptom calendar.
- Risk factors such as increased imposed stress and specific personality profiles are not helpful in differentiating women with PMS from those without PMS.
- The selective serotonin reuptake inhibitors (SSRIs), particularly fluoxetine and sertraline, have been shown to be effective in treating PMS.
- The bulk of scientific evidence does not support the usefulness of natural progesterone or primrose oil in the treatment of PMS.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- The use of gonadotropin-releasing hormone (GnRH) agonists and surgical oophorectomy has been shown to be effective in PMS. However, the side effects of GnRH agonists and oophorectomy limit their usefulness in most patients.
- Treatment with the anxiolytic alprazolam is effective in some patients. Its side effects limit its use as a first-line approach.
- Carbohydrate-rich foods and beverages may improve mood symptoms and food cravings in women with PMS and are a reasonable first-line approach in many patients.
- Calcium supplements have been shown to be effective in treatment of PMS.
- Magnesium, vitamin B_6, and vitamin E may have minimal effectiveness in the treatment of PMS.
- Oral contraceptives may improve physical symptoms of PMS.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Supportive therapy is central to the management of all PMS patients.
- Aerobic exercise can be recommended to PMS patients.
- As an overall clinical approach, treatments should be employed in increasing orders of complexity. Using this principle, in most cases, the therapies should be used in the following order:
    - Step 1. Supportive therapy, complex carbohydrate diet, aerobic exercise, nutritional supplements (calcium, magnesium, vitamin E), spironolactone
    - Step 2. The SSRIs (fluoxetine or sertraline as the initial choice); for women who do not respond, consider an anxiolytic for specific symptoms
    - Step 3. Hormonal ovulation suppression (oral contraceptives or GnRH agonists)

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

Level A - Recommendations are based on good and consistent scientific evidence.

Level B - Recommendations are based on limited or inconsistent scientific evidence.

Level C - Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Appropriate management of premenstrual syndrome (PMS)

Benefits of Specific Treatments

- Supportive therapy: Women anecdotally report relief when they are informed that PMS is a common medical problem with a physiologic basis. In one small comparative study, relaxation therapy had its greatest effects in women with the most severe symptoms.
- Aerobic exercise has been found in epidemiologic studies to be associated with fewer reported PMS symptoms, and exercise has been found to reduce symptoms among people with depressive disorders. Limited evidence supports a similar role for this intervention in PMS. In a 3-month randomized trial of 23 women with prospectively diagnosed PMS, the group taking regular moderate aerobic exercise reported more improvement than the control group who did nonaerobic exercise. In another small prospective but not randomized study, two groups of women who exercised aerobically reported fewer PMS symptoms at the end of a 6-month trial than did a nonexercising comparison group.
- Calcium and magnesium have each been shown to be effective in the treatment of PMS. However, most of these trials have tested small numbers of patients and must be validated in larger trials before strong evidence-based recommendations can be made. One large well-designed multicenter trail of 466 women with PMS reported that 1,200 mg/d of calcium carbonate was efficacious in reducing total symptom scores. Two small trials have found that 200 to 400 mg of magnesium may be somewhat effective.
- Vitamin E: In one randomized, double-blind, controlled study comparing vitamin E 400 IU/d during the luteal phase with placebo, vitamin E was found to improve significantly affective and somatic symptoms in PMS patients.
- Carbohydrate-rich beverages: In one study, mood symptomatology and carbohydrate food cravings were shown to be improved by carbohydrate-rich beverages.
- Selective serotonin reuptake inhibitors: A large 6-month multicenter trial and several smaller, shorter-duration placebo-controlled trials have consistently reported the efficacy of fluoxetine administered throughout the menstrual cycle. Intermittent therapy, with an SSRI given only during the symptomatic phase, also has been efficacious in several small, randomized, double-blind, placebo-controlled trials.

- Alprazolam: Some placebo-controlled trials have shown alprazolam, an anxiolytic medication, to be effective as a treatment of PMS. Alprazolam may potentially be useful for PMS patients who are not relieved by other interventions. It may be especially useful if agitation and anxiety are the primary symptoms.
- Spironolactone: Several randomized, double-blind, placebo-controlled trials have shown a significant reduction in somatic and affective complaints with spironolactone.
- Oral contraceptives: In one randomized trial, a triphasic formulation reduced physical symptoms but not mood alterations.
- Gonadotropin-releasing hormone (GnRH) agonists: Improvement in PMS symptoms with GnRH agonists has been reported in the majority of well-designed studies. In one small rigorous study, administration of the GnRH agonist resulted in an improvement of approximately 75% in luteal phase symptom scores.

POTENTIAL HARMS

Side Effects of Treatment

- Vitamin B_6: Dosages in excess of 100 mg/d may cause medical harm, including peripheral neuropathy.
- Fluoxetine: Side effects associated with fluoxetine include headaches, nausea, and jitteriness. Insomnia often can be avoided by early-morning dosing or, if appropriate, by lowering the dosage. Decreased libido also is problematic in some patients.
- Alprazolam: There is a potential for dependency and development of tolerance with this medication, especially if dosing is not limited to the luteal phase. Sedation also can be a bothersome side effect in some patients, and withdrawals can be problematic.
- Oral contraceptives: Many patients experience breast tenderness, nausea, mood alterations, and other side effects the first few months of oral contraceptive use.
- Gonadotropin-releasing hormone (GnRH) agonists: The hypoestrogenic side effects and cost of GnRH agonists limit the usefulness of this method except in severe cases of premenstrual syndrome (PMS) unresponsive to other treatment. If this therapy is to be used for more than a few months, bone loss becomes a concern.
- Bilateral salpingo-oophorectomy: Surgery for PMS is controversial because it is irreversible, it is associated with morbidity and mortality, and the resulting hypoestrogenemia must be addressed to prevent long-term complications.

QUALIFYING STATEMENTS

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- These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

- Establishing evidence-based recommendations for premenstrual syndrome (PMS) is difficult for many reasons. Definitions and inclusion criteria for PMS vary significantly among studies. In addition, the PMS patient populations studied in rigorous trials also may be different from the patient population of a given practitioner. For example, many recent PMS trials have properly included only women with the full-blown syndrome, including mood-related symptoms, whereas many women seek care from their practitioners for a less severe condition, with primarily somatic symptoms.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Apr (reviewed 2005)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2005, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 14, 2004. The information was verified by the guideline developer on December 8, 2004. This summary was updated by ECRI on October 3, 2005, following the U.S. Food and Drug Administration advisory on Paxil (paroxetine). This summary was updated by ECRI on December 12, 2005, following the U.S. Food and Drug Administration advisory on Paroxetine HCL - Paxil and generic paroxetine. This summary was updated by ECRI on May 31, 2006 following the U.S. Food and Drug Administration advisory on Paxil (paroxetine hydrochloride).

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